

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

KIDS FIRST OF FLORIDA, INC.,

Plaintiff,

**MCKESSON CORPORATION; CARDINAL
HEALTH, INC.; AMERISOURCEBERGEN
CORPORATION; AMERISOURCEBERGEN
DRUG CORPORATION; PURDUE
PHARMA L.P.; PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY,
INC.; TEVA PHARMACEUTICALS
INDUSTRIES, LTD; TEVA
PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; ENDO
HEALTH SOLUTIONS INC.; ENDO
PHARMACEUTICALS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS LLC;
ACTAVIS PHARMA, INC. f/k/a WATSON
PHARMA, INC.; ALLERGAN PLC f/k/a
ACTAVIS PLC; ALLERGAN FINANCE,
LLC; MALLINCKRODT, PLC, d/b/a
MALLINCKRODT PHARMACEUTICALS;
MALLINCKRODT, LLC,**

Defendants.

Case No.: _____

COMPLAINT

JURY TRIAL DEMANDED

COMPLAINT (JURY TRIAL DEMANDED)

Comes now the Plaintiff, Kids First of Florida, Inc., a Florida not-for-profit corporation (hereinafter referred to as “KFF”), by and through its attorneys, and files suit against the Defendants and would show as follows:

INTRODUCTION

1. The addiction epidemic of prescription opioid abuse in the United States has caused providers of substance abuse treatment and re-entry services to offenders, ex-felons, and probation populations, including KFF, extraordinary economic damages, substantial loss of resources, and capital costs. This epidemic is the largest health care crisis in U.S. history, and it has financially harmed KFF to the point that it has hampered its ability to provide re-entry services, including substance abuse and addiction treatment.

2. Prescription opioids are deadlier than heroin. According to the National Institutes of Health, prescription opioids kill almost twice as many people in the United States as heroin. Prescription opioids and related drug overdose deaths surpass car accident deaths in the U.S. The costs to health care are overwhelming.

3. This epidemic and its consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry and the Defendants who manufacture the prescription opioids. These Defendants have profited greatly by allowing the geographic areas that KFF serves to become flooded with prescription opioids.

4. The drug distribution industry is supposed to serve as a "check" in the drug delivery system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants woefully failed in this duty, instead consciously ignoring known or knowable problems and data in their supply chains.

5. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent patients who became addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly

fulfilling suspicious orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale and before dispensing the pills.

6. Defendants' wrongful conduct has allowed millions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in the demographic area of KFF. This is characterized as "opioid diversion." Acting against their common law and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, unknowing patients and unauthorized opioid users have ready access to illicit sources of diverted opioids.

7. For years, Defendants and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion, including the deaths and health ruination of hundreds of thousands of citizens. Substantial expenditures by KFF in dealing with the problem have gone un-recouped and unreimbursed. All the Defendants in this action share responsibility for perpetuating the epidemic.

8. Defendants have foreseeably caused damages to KFF including the unreimbursed and/or un-recouped costs of providing: (a) opioid addiction treatment; (b) counseling and rehabilitation services; (c) re-entry services; (d) lost opportunity costs; (e) the diversion of assets from the provision of other needed health treatments; and (f) increased human resources costs.

9. KFF brings this Complaint for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure KFF.

PARTIES

10. The Plaintiff, KFF, is a Florida not-for-profit corporation with its principal place of business in Orange Park, Clay County, Florida. KFF was formed in 2003 and is one of the leading agencies in the state of Florida for delivering services to children and families dealing with issues of abuse and neglect. KFF provides child welfare and foster care services to the residents of Clay County, Florida. KFF's foster care-related services include, but are not limited to: protective supervision; foster parent recruitment, training and placements; the promotion of adoption for children whose parental ties have been severed, and; specialized assistance for teens and young adults who are about to "age out" of the foster care system. KFF's foster care services have experienced a significant adverse impact due to the opioid crisis. Opioid addiction has caused a dramatic increase in the number of parents unable to care for their children, and accordingly, the need for foster care for their children has increased dramatically. As a result, KFF has had to expend significant additional resources.

11. McKesson Corporation ("McKesson") has its principal place of business in San Francisco, California and is incorporated under the laws of Delaware. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area served by KFF.

12. Cardinal Health, Inc. ("Cardinal") has its principal place of business in Ohio and is incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area served by KFF.

13. AmerisourceBergen Corporation ("AmerisourceBergen") has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant

times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area served by KFF.

14. AmerisourceBergen Drug Corporation (“AmerisourceBergen Drug”) has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen Drug has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area served by KFF.

15. McKesson, Cardinal, AmerisourceBergen, and AmerisourceBergen Drug are collectively referred to hereinafter as “Distributor Defendants.”

16. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, “Purdue”). Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S., including the geographic area served by KFF. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

17. Cephalon, Inc. (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. Actiq and Fentora have been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer

pain.” In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

18. Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

19. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in the geographic area served by KFF, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in the geographic area served by KFF, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon’s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own. Through interrelated operations like these, Teva Ltd. operates in Washington and the rest of the U.S. through its subsidiaries Cephalon and Teva USA. The U.S. is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the

United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as “Cephalon.”)

20. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals’ drugs and Janssen’s profits inure to J&J’s benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J hereinafter are collectively referred to as “Janssen.”). Janssen manufactures, promotes, sells, and distributes drugs, including the opioid Duragesic, in the U.S., including Washington. Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

21. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of

Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are collectively referred to as “Endo.”) Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S., including the other geographic area served by KFF. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S., including the geographic area served by KFF, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

22. Allergan plc (f/k/a Actavis, plc. f/k/a Watson Pharmaceuticals, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.) is a Nevada limited liability company with its principal place of business in Parsippany, New Jersey. Allergan Finance, LLC is a wholly owned subsidiary of Allergan plc, which markets and sells Allergan plc’s drugs in the United States. Allergan plc and Allergan Finance, LLC are collectively referred to herein as “Allergan.” Allergan manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and has also manufactured, promoted, sold, the branded drugs generic versions of Duragesic and Opana.

23. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Parsippany, New Jersey.

24. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with

its principal place of business in New Jersey. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis LLC's sole member is Actavis US Holding LLC, a limited liability company organized under the laws of Delaware and Actavis US Holding LLC's sole member is Watson Laboratories, Inc. These defendants were owned by Allergan plc until August of 2016 at which point they were sold to Teva. Until then, Allergan plc used Actavis Pharma, Inc. and Actavis LLC to market and sell its drugs in the United States. Upon information and belief, Allergan plc has therefore exercised control over and derived financial benefit from the marketing, sales, and profits of Allergan/Actavis products. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as "Actavis.").

25. Mallinckrodt plc is a public limited company, headquartered in the United Kingdom, which does business as Mallinckrodt Pharmaceuticals with its principal place of business in the United States in Hazelwood, Missouri, is one of the largest manufacturers of the generic opioid oxycodone. Mallinckrodt, LLC is a Delaware limited liability company, also doing business as Mallinckrodt Pharmaceuticals, with its principal place of business in the United States in Hazelwood, Missouri. Mallinckrodt plc and Mallinckrodt LLC are collectively referred to herein as "Mallinckrodt." Mallinckrodt is one of the largest manufacturers of the generic opioid oxycodone.

26. Purdue, Cephalon, Janssen, Endo, Actavis, and Mallinckrodt are collectively referred to hereinafter as the "Pharmaceutical Defendants."

JURISDICTION AND VENUE

27. Jurisdiction of this Court arises under the laws of the United States, 28 U.S.C. §

1332, as the parties are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of attorney's fees and costs.

28. Defendants have engaged in conduct and activities over a long time, systematically, individually, jointly, and severally, in the geographic area served by KFF that have caused all of KFF's damages and all of which form the bases of the causes of action in this Complaint as against Defendants. Defendants have committed multiple torts and breaches within the geographic areas which KFF serves, repeatedly and systematically.

29. Defendants, for a long time, repeatedly and systematically, have substantial contacts and business relationships with KFF and the individuals served by KFF, including consensual relationships and contracts performed within the geographic area served by KFF, some or all of which form the bases of the causes of action in this Complaint as against Defendants.

30. This Court has personal jurisdiction over Defendants, each of which has committed torts, in part or whole, within the State of Florida and the geographic area served by KFF, as alleged herein. Moreover, Defendants have substantial contacts and business dealings directly with KFF by virtue of their distribution, dispensing, and sales of prescription opioids. All causes of action herein relate to Defendants' wrongful actions, conduct, and omissions committed against KFF, and the consequences and damages related to said wrongful actions, conduct, and omissions.

31. Venue is proper in this Court pursuant to 28 U.S.C. 1391(b) in that a substantial part of the events giving rise to the claims occurred in the Middle District of Florida. Plaintiff states that but for the Order permitting direct filing into the Northern District of Ohio pursuant to Case Management Order No. 1, dated April 11, 2018, Plaintiff would have filed in the U.S.

District Court, Middle District of Florida.

BACKGROUND FACTS

32. Opioid means "opium - like" and the term includes all drugs derived in whole or in part from the opium poppy.

33. The United States Food and Drug Administration's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."

34. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

35. Before the epidemic of Defendants' prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

PHARMACEUTICAL DEFENDANTS' WRONGFUL CONDUCT

36. To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and deceptive marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that created the “new” market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including those in the geographic areas served by KFF.

37. The Pharmaceutical Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Florida. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout KFF’s geographic areas and patient demographics.

38. The Pharmaceutical Defendants’ direct and branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue ran a series of ads, called “Pain Vignettes,” for OxyContin that featured chronic pain patients and recommended OxyContin for each. One ad

described a “54-year-old writer with osteoarthritis of the hands” and implied that OxyContin would help the writer work more effectively. While Endo and Purdue agreed in 2015-16 to stop these particularly misleading representations in New York, they continued to disseminate them in Florida.

39. The Pharmaceutical Defendants also promoted the use of opioids for chronic pain through “detailers” – sophisticated and specially trained sales representatives who visited individual doctors and medical staff, and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost \$200 million on detailing branded opioids to doctors.

40. The FDA has cited at least one of these Defendants for deceptive promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated “Dear Doctor” letter required Actavis to inform doctors that “Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian],” including the risk of “[m]isuse, [a]buse, and [d]iversion of [o]pioids” and, specifically, the risk that “[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.”

41. The Pharmaceutical Defendants invited doctors to participate, for payment and other remuneration, on and in speakers’ bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by these Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants’ prior misrepresentations about the risks and benefits of opioids.

42. The Pharmaceutical Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

43. The Pharmaceutical Defendants have had unified marketing plans and strategies from state to state, including Florida. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.

44. The Pharmaceutical Defendants deceptively marketed opioids in Florida through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

45. The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the deceptive messages came from an independent and objective source.

46. The Pharmaceutical Defendants' deceptive unbranded marketing also contradicted their branded materials reviewed by the FDA.

47. The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a

number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

48. These Defendants entered into and/or benefitted from relationships with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society (“APS”), American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), American Society of Pain Education (“ASPE”), National Pain Foundation (“NPF”), and Pain & Policy Studies Group (“PPSG”).

49. The Pharmaceutical Defendants collaborated, through the aforementioned organizations and groups, to spread deceptive messages about the risks and benefits of long-term opioid therapy.

50. To convince doctors and patients in Florida that opioids can and should be used to treat chronic pain, these Defendants had to persuade them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

51. To convince doctors and patients that opioids are safe, the Pharmaceutical Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low- risk because most patients would not become addicted, and

because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

52. The Pharmaceutical Defendants falsely claimed that the risk of opioid addiction is low, and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these false and deceptive claims by opioid manufacturers are: (a) Actavis employed a patient education brochure that falsely claimed opioid addiction is “less likely if you have never had an addiction problem;” (b) Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain*, falsely claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, *Painknowledge.com*, which falsely claimed that “[p]eople who take opioids as prescribed usually do not become addicted”; (d) Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: “most people do not develop an addiction problem;” (e) Janssen distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* which described as “myth” the claim that opioids are addictive; (f) a Janssen website falsely claimed that concerns about opioid addiction are “overestimated;” and (g) Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – that falsely claims that pain is undertreated due to “misconceptions about opioid addiction.”

53. These claims are contrary to longstanding scientific evidence, as the FDA and

CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

54. The FDA further exposed the falsity of the Pharmaceutical Defendants’ claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

55. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.” Endo had claimed on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found no evidence for that statement. Consistent with this, Endo agreed not

to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. This agreement, however, did not extend to Florida.

56. The Pharmaceutical Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon “pseudo-addiction” – a term used by Dr. David Haddox, who went to work for Purdue, and Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue. Defendants falsely claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these deceptive claims are: (a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing*, which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated;” (c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudo-addiction by teaching that a patient’s aberrant behavior was the result of untreated pain; (d) Purdue sponsored a deceptive CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse* in which a clinician notes that because of pseudo-addiction, a doctor should not assume the patient is addicted.

57. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer- term use,” and that physicians should “reassess[]

pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”

58. The Pharmaceutical Defendants falsely instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Pharmaceutical Defendants’ misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these deceptive claims are: (a) an Endo supplement in the *Journal of Family Practice* emphasized the effectiveness of screening tools to avoid addictions; (b) Purdue’s webinar, *Managing Patient’s Opioid Use: Balancing the Need and Risk*, claimed that screening tools, urine tests, and patient agreements prevent “overuse of prescriptions” and “overdose deaths;” (c) Purdue represented in scientific conferences that “bad apple” patients – and not opioids – were the source of the addiction crisis, when in fact the “bad apples” were the Defendants.

59. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” The Guideline emphasizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”

60. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Pharmaceutical Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

61. A CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, that claimed "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," without mentioning any known or foreseeable issues.

62. Pharmaceutical Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.” The Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient's

response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

63. The Pharmaceutical Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example: (a) an Actavis patient brochure stated - “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction;” (b) Cephalon and Purdue sponsored *APF’s Treatment Options: A Guide for People Living with Pain*, claiming that some patients need larger doses of opioids, with “no ceiling dose” for appropriate treatment of severe, chronic pain; (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until “you are on the right dose of medication for your pain;” (d) an Endo pamphlet *Understanding Your Pain: Taking Oral Opioid Analgesics*, stated “The dose can be increased. . . . You won’t ‘run out’ of pain relief;” (e) a Janssen patient education guide *Finding Relief: Pain Management for Older Adults* listed dosage limitations as “disadvantages” of other pain medicines yet omitted any discussion of risks of increased opioid dosages; (f) Purdue’s In the Face of Pain website promotes the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will; (g) Purdue’s *A Policymaker’s Guide to Understanding Pain & Its Management* stated that dosage escalations are “sometimes

necessary,” even unlimited ones, but did not disclose the risks from high opioid dosages; (h) a Purdue CME entitled *Overview of Management Options* taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages; (i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

64. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.” More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC states that “there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages.” That is why the CDC advises doctors to “avoid increasing dosages” above 90 morphine milligram equivalents per day.

65. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

66. Pharmaceutical Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

67. Pharmaceutical Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo’s

advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

68. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

69. These numerous, longstanding misrepresentations minimizing the risks of long-term opioid use persuaded doctors and patients to discount or ignore the true risks. Pharmaceutical Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of

adequate and well-controlled studies of opioids use longer than 12 weeks.” Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

70. For example, the Pharmaceutical Defendants falsely claimed that long-term opioid use improved patients’ function and quality of life, including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives; (b) an Endo advertisement that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, portraying seemingly healthy, unimpaired persons; (c) a Janssen patient education guide *Finding Relief: Pain Management for Older Adults* stated as “a fact” that “opioids may make it easier for people to live normally” such as sleeping peacefully, working, recreation, sex, walking, and climbing stairs; (d) Purdue advertisements of OxyContin entitled “Pain vignettes” implied that OxyContin improves patients’ function; (e) *Responsible Opioid Prescribing*, by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function; (f) Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* counseling patients that opioids “give [pain patients] a quality of life we deserve;” (g) Endo’s NIPC website *painknowledge.com* claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse;” (h) Endo CMEs titled *Persistent Pain in the Older Patient* claimed that chronic opioid therapy had been “shown to reduce pain and improve depressive symptoms and cognitive functioning;” (i) Janssen sponsored, funded, and

edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function;” (j) Purdue’s *A Policymaker’s Guide to Understanding Pain & Its Management* claimed that “multiple clinical studies” had shown opioids as effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients; (k) Purdue’s, Cephalon’s, Endo’s, and Janssen’s sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

71. These claims find no support in the scientific literature. The 2016 CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . .”
- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

72. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

73. The 2016 CDC Guideline was not the first time a federal agency repudiated the Pharmaceutical Defendants’ claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that “[w]e are not aware of substantial evidence or substantial clinical

experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.” In 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

74. The Pharmaceutical Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

75. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all relevant times. According to Purdue’s own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is

released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial number” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

76. Purdue’s competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to “real” 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue’s sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

77. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

78. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for

which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain; (b) Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) in December 2011, Cephalon widely disseminated a journal supplement entitled “*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*” to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” – and not just cancer pain.

79. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

80. Purdue unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue’s sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate

the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue’s senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing so, Purdue protected its own profits at the expense of public health and safety.

81. The State of New York’s settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

82. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

83. Mallinckrodt, one of the largest manufacturers of the generic opioid oxycodone, recently agreed to pay a \$35 million penalty to resolve allegations by the U.S. Department of Justice that it failed to report suspicious drug orders. This is a record settlement of claims that a

pharmaceutical drug manufacturer failed to properly notify the U.S. Drug Enforcement Administration (“DEA”) of suspicious orders for drugs such as oxycodone. U.S. Attorney General Jeff Sessions said “Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street.” According to the Justice Department, from 2008 to 2011, Mallinckrodt supplied distributors increasingly excessive amounts of oxycodone pills without notifying the DEA of the suspicious orders. Those distributors in turn supplied the drugs to various U.S. pharmacies and pain clinics, the Justice Department said. Mallinckrodt, however, continues to deny culpability to the public and the medical community. Michael-Bryant Hicks, Mallinckrodt’s general counsel, said the company chose to settle “to eliminate the uncertainty, distraction and expense of litigation and to allow the company to focus on meeting the important needs of its patients and customers.”

84. As a part of their deceptive marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S. and the geographic areas served by KFF. For example, these Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants’ misrepresentations.

85. The Pharmaceutical Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. These Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore

concludes that there are “special risks of long-term opioid use for elderly patients” and recommends that doctors use “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

86. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned these Defendants of this, and these Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants’ misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

87. Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. These Defendants purposefully hid behind the

assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

88. The Pharmaceutical Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, fake independent groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Pharmaceutical Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

89. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions.

90. Thus, the Pharmaceutical Defendants successfully concealed from the medical community, patients, and health care providers facts sufficient to arouse suspicion of the claims that KFF now asserts. KFF did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

91. The Pharmaceutical Defendants' misrepresentations deceived doctors and patients

about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

92. The Pharmaceutical Defendants' deceptive marketing scheme caused and continues to cause doctors in Florida, and specifically in the geographic areas served by KFF to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. These Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

93. The Pharmaceutical Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

94. The escalating number of opioid prescriptions written by doctors who were deceived by the Pharmaceutical Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S., Florida, and in the geographic areas served by KFF. In August 2016, the U.S. Surgeon General

published an open letter to be sent to physicians nationwide, enlisting their help in combating this “urgent health crisis” and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the “devastating” results that followed, had “coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”

95. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

96. Contrary to the Pharmaceutical Defendants’ misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants’ representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients, who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors’ prescribing habits have played in the opioid epidemic.

97. Opioid-related death tolls are rising at such a rapid pace that cities and counties are unable to keep up logistically.

DISTRIBUTOR DEFENDANTS’ WRONGFUL CONDUCT

98. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies,

including Defendants Cardinal, McKesson, AmerisourceBergen, and AmerisourceBergen Drug, which together account for 85-90% of all revenues from drug distribution in the United States, an estimated \$378.4 billion in 2015. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

99. Manufacturer Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid “diversion” occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the pharmacy level when prescriptions are filled for any reason other than a legitimate medical purpose.

100. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

101. Diversion occurs at the pharmacies, including whenever a pharmacist fills a prescription despite having reason to believe it was not issued for a legitimate medical purpose or not in the usual course of practice. Some of the signs that a prescription may have been issued for an illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from different doctors (a/k/a doctor shopping), when they travel great distances between the doctor or their residence and the pharmacy to get the prescription filled, when they present multiple prescriptions for the largest dose of more than one controlled substance, or when there

are other "red flags" surrounding the transaction. These signs or "red flags" should trigger closer scrutiny of the prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication for purposes to treat a legitimate medical condition. In addition to diversion via prescription, opioids are also diverted from retail outlets when stolen by employees or others.

102. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

103. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

104. Every year, millions of people in the United States misuse and abuse opioid pain relievers that can lead to addiction, overdose and death. The overdose rate among Native Americans is significantly higher than the rest of the population.

105. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in the United States. Overdose deaths involving prescription opioids are at epidemic proportions, quadrupling since 1999, concomitant with sales of these prescriptions.

106. In 2011 overdose deaths from prescription opioids reached 16,917 people. In 2014 18,893 people died from a prescription opioid related overdose. In 2015, the number of deaths increased to 22,598, even despite increased public health announcements.

107. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using

prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with prescription opioid. The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin. Heroin deaths are on a tragic upswing: In 2015, over 12,989 people died from heroin overdose-up more than 20% from approximately 10,574 overdose deaths in 2014.

108. KFF has taken proactive measures in its own community to fight against prescription opioid abuse. Indeed, a critical aspect of KFF's mission is reducing opioid abuse within the population it serves.

109. Defendants' opioid diversion diminishes KFF's ability to combat other addiction issues, decreases productivity, decreases the likelihood of successful re-entry, increases criminal activity, increases recidivism, increases poverty, and consequently requires greater expenditures by KFF in treating opioid-addicted patients.

110. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

111. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et seq., the Florida Drug and Cosmetic Act ("FDCA"), Section 499.001, Florida Statutes, et seq., the Florida Comprehensive Drug Abuse Prevention and Control Act ("FCDAPCA"), Section 893.01, Florida Statutes, et seq., and their implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants'

violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. The Distributor Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless disregard.

112. By violating the CSA, the FDCA, and the FCDAPCA, the Distributor Defendants are also liable under Florida's Unfair and Deceptive Trade Practices Act, which specifically makes it a civil offense to violate statutes affecting or impacting chattels bought for medical purposes.

113. The CSA and FDCA create a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 4572. The FDCA includes requirements for registration with and reporting to both DEA and the Florida Department of Business and Professional Regulation ("FDBPR") in order to establish a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user.

114. Accordingly, the CSA and FDCA act as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA and FDCA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

115. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream

suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

116. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' controlled substances, acquisition transactions, and distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

117. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (1); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

118. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.21(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

119. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

120. For years the Distributor Defendants have known of the problems and consequences of opioid diversion in the supply chain.

121. The Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

122. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

123. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

124. For example, a Cardinal executive claimed that Cardinal uses “advanced analytics” to monitor its supply chain. He further extolled that Cardinal was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity.” (emphasis added).

125. McKesson has publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders” and claimed it is “deeply passionate about curbing the opioid epidemic in our Country.”

126. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

127. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

128. The Distributors Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction have resulted in numerous civil fines and other penalties recovered by state and federal agencies- including actions by the DEA related to violations of the federal Controlled Substances Act.

129. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-

million-dollar settlement with Cardinal for violations of the Controlled Substances Act. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

130. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a \$13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay \$150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

131. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for

legitimate medical, scientific and industrial purposes.”

132. Relying upon state laws and regulation, various State Boards of Pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations.

133. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

134. The Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to KFF.

135. The Distributor Defendants have supplied massive quantities of prescription opioids in and around the geographic areas served by KFF with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

136. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into the geographic areas served by KFF was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

137. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees;

providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the geographic areas served by KFF; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

138. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing the individuals served by KFF and in the geographic areas it serves to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses.

139. On information and belief, the compensation the Distributor Defendants provided to a certain number of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the individuals served by KFF and in the geographic areas it serves, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

140. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the geographic areas served by KFF with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

141. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable that the costs of these injuries will be shouldered by KFF.

142. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid costs of KFF, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

143. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed to individuals served by KFF were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties, and KFF.

144. The Distributor Defendants were aware of widespread prescription opioid abuse of persons who would become patients of KFF, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in the geographic areas served by KFF—and in such quantities, and with such frequency—that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

145. If any of the Distributor Defendants adhered to effective controls to guard against diversion, KFF would have avoided significant damages.

146. The Distributor Defendants made substantial profits over the years based on the diversion of opioids affecting KFF. Their participation and cooperation in a common enterprise has foreseeably caused damages to KFF. The Distributor Defendants knew full well that KFF would be unjustly forced to bear the costs of these injuries and damages.

147. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for KFF. Their conduct poses a continuing economic threat to KFF.

148. The Pharmaceutical Defendants, including Mallinckrodt, have engaged in similar wrongful conduct as alleged hereinabove as the Distributor Defendants.

COUNT I: NUISANCE

149. The Plaintiff reasserts the allegations of paragraphs 1 through 148 as if set forth fully herein.

150. The nuisance is the over-saturation of opioids in the patient population of KFF and in the geographic areas served by KFF for non-medical purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

151. All Defendants substantially participated in nuisance-causing activities.

152. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of KFF, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

153. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

154. Defendants' activities unreasonably interfere with the economic rights of KFF.

155. The Defendants' interference with these rights of KFF is unreasonable because it:

- a. Has harmed and will continue to harm the public health services of and public peace of KFF;
- b. Has harmed and will continue to harm the communities and neighborhoods which KFF services;
- c. Is proscribed by statutes and regulation, including the CSA and FDCA, pharmacy regulations, and the consumer protection statute;
- d. Is of a continuing nature and it has produced long-lasting effects; and

e. Defendants have reason to know their conduct has a significant effect upon KFF.

156. The nuisance undermines public health, quality of life, and safety. It has resulted in increased crime and property damage. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities.

157. The resources of KFF are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other areas related to re-entry services.

158. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions.

159. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids in the geographic area served by KFF.

160. As a direct and proximate result of the nuisance, KFF has sustained economic harm by spending a substantial amount of money trying to remedy and abate the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of treatment services.

161. KFF has also suffered unique harms different from individual opioid users and governmental entities at large, namely, that KFF has been harmed in its proprietary interests.

162. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented.

163. Defendants should be required to pay the expenses KFF has incurred or will incur in the future to fully abate the nuisance.

COUNT II: NEGLIGENCE AND GROSS NEGLIGENCE

164. The Plaintiff reasserts the allegations of paragraphs 1 through 148 as if set forth fully herein.

165. Defendants owe a non-delegable duty to KFF to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

166. There is no social value to Defendants' challenged behavior. In fact, Defendants' entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against the law.

167. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of KFF and the individuals it serves.

168. Defendants' behavior caused a substantial injury and damage to KFF.

169. Defendants' conduct fell below the reasonable standard of care and was negligent. Their negligent acts include:

- a. Consciously oversupplying the market in and around the geographic areas served by KFF with highly-addictive prescription opioids;
- b. Using unsafe distribution and dispensing practices;
- c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;
- d. Disregarding precautionary measures built into the CSA, pharmacy board regulations, and applicable law;
- e. Failing to properly train or investigate their employees;

- f. Failing to properly review prescription orders for red flags;
- g. Failing to report suspicious orders or refuse to fill them;
- h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances; and
- i. Failing to police the integrity of their supply chains; and
- j. Creating misleading information with the intention of having prescribers rely upon it.

170. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

171. Each Defendant sold prescription opioids in the supply chain knowing (a) there was a substantial likelihood many of the sales were for non-medical purposes and, (b) opioids are an inherently dangerous product when used for non-medical purposes, and (c) that every patient, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

172. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

173. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

174. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of: corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

175. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-a-vis KFF and its patient communities. Defendants owe a special duty to KFF. That duty cannot be delegated to another party.

176. KFF is without fault, and the injuries to KFF would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

177. The aforementioned conduct of Defendants proximately caused damage to KFF.

COUNT III: UNJUST ENRICHMENT

178. Plaintiff reasserts the allegations of paragraphs 1 through 148 as if set forth fully herein.

179. KFF has expended substantial amounts of money to address, remedy and/or mitigate the societal harms caused by Defendants' conduct.

180. The expenditures by KFF in providing treatment services to people who use opioids have added to Defendants' wealth. The expenditures by KFF have helped sustain Defendants' businesses.

181. KFF has conferred a benefit upon Defendants, by paying for what may be called Defendants' externalities - the costs of the harm caused by Defendants' negligent distribution and sales practices.

182. Defendants are aware of this obvious benefit, and that retention of this benefit is unjust.

183. Defendants made substantial profits while fueling the prescription drug epidemic in the geographic area served by KFF.

184. Defendants continue to receive considerable profits from the distribution of controlled substances in the geographic area serviced by KFF.

185. Defendants have been unjustly enriched by their negligent, intentional, malicious, oppressive, illegal and unethical acts, omissions, and wrongdoing.

186. It would be inequitable to allow Defendants to retain the benefit or financial advantage of their wrongdoing.

187. KFF demands judgment against each Defendant for restitution, disgorgement, and any other relief allowed in law or equity.

COUNT IV: COMMON LAW FRAUD

(AS TO PHARMACEUTICAL DEFENDANTS ONLY)

188. Plaintiff reasserts the allegations of paragraphs 1 through 148 as if set forth fully herein.

189. Pharmaceutical Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

190. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following: (a) advertising that opioids improved long-term functioning long-term and were suitable for the treatment of chronic non-cancer pain; (b) promoting the concept of pseudo-addiction; (c) brochures concerning indicators of possible opioid abuse; (d) suitability of opioids for high-risk patients; (e) publications presenting an unbalanced treatment of the long-

term and dose-dependent risks of opioids versus NSAIDs; (f) concealment of funding of pro-opioid KOL doctors regarding treatment for chronic non-cancer pain; (g) downplaying of the risks of opioid addiction; (h) CMEs promoting the use of opioids to treat chronic non-cancer pain; (i) promotion of misleading scientific studies regarding the safety and efficacy of opioids for long-term treatment of chronic non-cancer pain; (j) misuse and promotion of data to mask the true safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including rates of abuse and addiction and the lack of validation for long-term efficacy; (k) misleading statements in education materials for Florida hospital doctors and staff under guise of educating them on new pain standards; (l) in-person detailing; and (m) withholding from Florida law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs.

191. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following: (a) false patient education materials; (b) advertising the ability of opioids to improve function long-term and the efficacy of opioids long-term for the treatment of chronic non-cancer pain; (c) promoting chronic opioid therapy as safe and effective for long term use for high- risk patients; (d) Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse; (e) concealing the true risk of addiction and promoting the misleading concept of pseudo-addiction; (f) promoting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (g) secretly funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (h) funding pro-opioid pain organizations responsible for egregious misrepresentations concerning

the use of opioids to treat chronic non-cancer pain; (i) downplaying the risks of opioid addiction in the elderly; (j) CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (k) misleading scientific studies concluding opioids are safe and effective for the long-term treatment of chronic non-cancer pain and quality of life, while concealing contrary data; (l) funding and promoting pro-opioid KOLs concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudo-addiction; (m) manipulation of data regarding safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and (n) in-person detailing.

192. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following: (a) patient education materials containing deceptive statements regarding the suitability, benefits, and efficacy of opioids; (b) stating that opioids were safe and effective for the long-term treatment of chronic non-cancer pain; (c) stating that opioids improve quality of life, while concealing contrary data; (d) concealing the true risk of addiction; (e) promoting the deceptive concept of pseudo-addiction; (f) promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious, and concealing this information; (g) presenting to the public and doctors an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (h) funding pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; (i) funding pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain; (j) using CMEs to promote false statements concerning the use of opioids to treat chronic non-cancer pain and; (k) in-person detailing.

193. Defendant Cephalon made and/or disseminated untrue, false, and deceptive statements minimizing the risk of addiction of opioids, promoting the concept of pseudo-addiction, advocating the use of opioids for chronic non-cancer pain, funding misleading CMEs, KOL doctors, and pain organizations, minimizing the addictiveness of Cephalon's potent rapid-onset opioids, and promoting the suitability of Cephalon's rapid-onset opioids to general practitioners, neurologists, sports medicine specialists, and workers' compensation programs.

194. Defendant Actavis and Mallinckrodt made and/or disseminated deceptive statements, including, but not limited to, the following: (a) promotion of use of opioids to treat chronic non-cancer pain to Florida prescribers through in-person detailing; (b) advertising that opioids were safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improved quality of life; and (c) advertising that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain.

195. These false representations and concealments were reasonably calculated to deceive prescribing physicians in the geographic areas served by KFF, were made with the intent to deceive, and did in fact deceive physicians who prescribed opioids for chronic pain.

196. But for these false representations and concealments of material fact, KFF would not have incurred substantial costs and economic loss.

197. As a direct and proximate cause of the Pharmaceutical Defendants' fraudulent conduct, KFF has suffered damages.

COUNT V: CIVIL CONSPIRACY

198. Plaintiff reasserts the allegations of paragraphs 1 through 148 as if fully set out herein.

199. The Pharmaceutical Defendants continuously supplied prescription opioids to the Distributor Defendants despite having actual or constructive knowledge that said Distributors were habitually breaching their duties under the law.

200. Without the Distributor Defendants' supply of prescription opioids, pharmacies would not be able to fill and dispense the increasing number of prescription opioids throughout the geographic areas served by KFF.

201. Pharmacies continuously paid the Distributor Defendants to supply large quantities of prescription opioids in order to satisfy the demand for the drugs.

202. No Defendant in this opioid network would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party, and none would have succeeded so significantly without engaging in the wrongful conduct as herein alleged.

203. The Pharmaceutical Defendants likewise benefitted from this distribution conspiracy in that the more pervasive opioid diversion became, the more the Pharmaceutical Defendants profited. Despite access to the same information in the hands of the Distributor Defendants, the Pharmaceutical Defendants ignored the warning signs of opioid diversion.

204. As a result of the concerted actions between and among the Defendants, KFF has suffered damages.

205. KFF demands judgment against each Defendant for compensatory damages.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff KFF prays that the Court grant the following relief:

(a) Injunctive Relief as against the Defendants for their wrongful, tortious, and illegal activities as alleged hereinabove;

- (b) Compensatory, consequential, and incidental damages;
- (c) All available equitable remedies, including restitution and disgorgement of revenue and profits;
- (d) Punitive damages;
- (e) Attorneys' fees and all costs and expenses related to this civil action; and
- (f) All such other relief this Court and/or jury deems just and fair;
- (g) Trial by jury for all counts so triable.

Dated this 26th day of September, 2018.

Respectfully Submitted,

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